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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/406,473	09/27/99	PACETTI	M-735515

QM12/1012  
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EXAMINER  
THANH, L

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/406,473

Applicant(s)

PACETTI, STEPHEN D.

Examiner

LoAn H Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 11-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Claims 11-47 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7 & 9.

An action on the merits now follows.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear if Applicant is claiming the combination of the "a sheath" and the "device", or the subcombination of the "sheath" alone. This lack of definiteness arises from the clear indication in the preamble that Applicant intends to claim only the above subcombination, but Applicant goes on in the claim(s) to positively recite the combination. The claim is considered as having been drawn to the combination. If Applicant indicated by amendment that the combination claim is the intention, the language in the preamble should be made consistent with the language in the body. If indicated that the intent is to claim the subcombination only, the body of the claim must be amended to remove any positive recitation of the combination.

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Applicant has only functionally recited the device but applicant continues to positively recite the device.

Claim 8 is vague and indefinite because it is unclear what is intended by DS.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al. (U.S. Patent No. 5,700,286).

Tartaglia et al. teach a sheath having a hollow body wherein the body comprises a polymeric layer.

Claims 1,4,5 rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent No. 5,306,246).

Sahatjian et al. discloses a sheath comprising a hollow body comprising a layer which is a polymeric material selected from a group such as polyolefin, polyethylene, and polyesters.

Claims 1,4, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shee (U.S. Patent No. 4,721,204).

Shee discloses a sheath having a hollow body and a layer made up of polyvinyl chloride or cellulose acetate to contain the released liquid. See col. 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-7,9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sablotsky (U.S. Patent No. 4,585,452).

Sablotsky teaches a transdermal systemic dosage with a layer that prevents therapeutic substance from significantly absorbing into the body. Sablotsky teaches the specifics of the polymeric material being polyolefins, polyethylenes, polyvinyl chloride, polyvinylidene chloride, polyethylene terephthalate, polyurethane and nylon. Further, the material having a glass transition temperature above storage temperature.

However, Sablotsky is silent to the sheath being a hollow body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of the device as a mere design choice. The shape of the layer would be modified to the applicable shape of the device in which it was protecting. The instant disclosure describes the sheath to having a hollow body as being merely preferable and does not describe it as contributing any unexpected result to the medical device.

As to claim 7, it is well known in the art to make a substance non-polar is to mix the substance with hydrocarbons, silicones, fluorosilicones and mixtures thereof. It would have a manufacturing choice to make a substance more dissolvable in water or oil.

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As to claim 10, Sablotsky discloses the material being nylon but is silent to the nylon being nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon and mixtures thereof. It would have been an obvious design choice to substitute one type of nylon for another to achieve the specific characteristic that is desired by the manufacturer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on 5:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on 703-308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

LT  
October 8, 2001



LoAn H Thanh  
Examiner  
Art Unit 3763



RICHARD K. SEIDEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700